MEDICATION GUIDE
LIVSAYIS™ (liv-SAY-iss)
(cemdisiran)
injection, for subcutaneous use

What is the most important information I should know about LIVSAYIS?

LIVSAYIS is a medicine that affects part of your immune system. LIVSAYIS may lower the ability of your immune system to fight certain infections.

- LIVSAYIS increases your chance of getting serious meningococcal infections caused by **Neisseria meningitidis** bacteria. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.
  - You must complete your meningococcal vaccines at least 2 weeks before your first dose of LIVSAYIS.
  - If you have not completed your meningococcal vaccines and LIVSAYIS must be started right away, you should receive the required vaccines as soon as possible.
  - If you have not been vaccinated and LIVSAYIS must be started right away, you must also receive antibiotics.
  - If you had a meningococcal vaccine in the past, you might need additional vaccination before starting LIVSAYIS. Your healthcare provider will decide if you need additional meningococcal vaccination.
  - Meningococcal vaccines do not prevent all meningococcal infections. **Call your healthcare provider or get emergency medical help right away if you get any of these signs and symptoms of a meningococcal infection:**
    - fever
    - fever and a rash
    - fever with high heart rate
    - headache with nausea or vomiting
    - headache and a fever
    - headache with a stiff neck or stiff back
    - confusion
    - muscle aches with flu-like symptoms
    - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 12 months after your last LIVSAYIS dose. Your risk of meningococcal infection may continue for several months after your last dose of LIVSAYIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

LIVSAYIS is only available through a program called the LIVSAYIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive LIVSAYIS, your healthcare provider must:

- enroll in the LIVSAYIS REMS program.
- counsel you about the risk of serious meningococcal infections.
- give you the **Patient Guide** that explains your risk of serious meningococcal infections.
- give you a **Patient Safety Card**. This card has important information about the signs and symptoms of meningococcal infections. You must carry this card at all times while you are being treated and for 12 months after your last dose of LIVSAYIS.
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria and that you receive antibiotics if you need to start LIVSAYIS right away and you are not up to date on your vaccines.

LIVSAYIS may also increase the risk of other types of serious infections, especially those caused by encapsulated bacteria, including **Streptococcus pneumoniae, Haemophilus influenzae,** and **Neisseria gonorrhoeae**.

- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.

Call your healthcare provider right away if you have new signs or symptoms of infection.

What is LIVSAYIS?

- LIVSAYIS is a prescription medicine used to treat a disease called generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody-positive.
- It is not known if LIVSAYIS is safe and effective in children.

Who should not receive LIVSAYIS?

- **Do not receive LIVSAYIS if you** have a serious meningococcal infection when you are starting LIVSAYIS treatment.

Before you receive LIVSAYIS, tell your healthcare provider about all your medical conditions, including if you:

- have an infection or fever.
- are pregnant or plan to be pregnant. It is not known whether LIVSAYIS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LIVSAYIS passes into your breast milk.

Tell your healthcare provider about medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive LIVSAYIS?

- LIVSAYIS will be given to you by your healthcare provider as an injection under the skin (subcutaneous injection).
- You will receive a total dose of 567 mg (given as 2 separate injections) under the skin every 3 months.

What are the possible side effects of LIVSAYIS?
LIVSAYIS may cause serious side effects, including:

- See **"What is the most important information I should know about LIVSAYIS?"**

The most common side effects in people with gMG treated with LIVSAYIS include:

- injection site reactions
- viral infections
- urinary tract infections

Tell your healthcare provider about any side effect that bothers you or that does not go away.
These are not all the possible side effects of LIVSAYIS.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LIVSAYIS.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about LIVSAYIS that is written for health professionals.

What are the ingredients of LIVSAYIS?
Active ingredient: cemdisiran
Inactive ingredients: water for injection. May contain either or both of the following to adjust the pH: sodium hydroxide, phosphoric acid.

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For more information about LIVSAYIS, go to www.LIVSAYIS.com or call 1- 844-548-7294

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